



PATENT
Docket No. SU103 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Application of Michael J. Precopio

Serial No. 10/519,372
Filed: 12/23/2004

Examiner: Neil Levy
Art Unit: 1615

Title: METHODS FOR TREATING ECTOPARASITE INFECTIONS ON THE
MAMMALIAN BODY

CERTIFICATE OF MAILING

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Henry E. Millson, Jr.
Typed or printed name of certifier

APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant's appeal brief, in triplicate, is transmitted herewith in accordance with

37 CFR 1.192.

Respectfully submitted,

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BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

The real party in interest is SCIELE PHARMA CAYMAN LTD., a company organized under the laws of the Cayman Islands, and having a place of business at Five Concourse Parkway, Suite 1800, Atlanta, Georgia, 30328.

RELATED APPEALS AND INTERFERENCES

none

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STATUS OF CLAIMS

The claims remaining in the application are claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63. The claims on appeal are all of the above claims. Claims 2, 10, 12, 14, 17, 19, 27-32, and 37-44 have been cancelled.

Claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, and 33-36 have been rejected under 35 USC 112, first paragraph.

Claims 45-48 and 50-63 have been rejected under 35 USC 102(b).

Claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 have been rejected under 35 USC 103(a).

Claims 1, 3-5, 8, 9, 13, 18, 20, 22-26, 33 have been rejected on the ground of nonstatutory obviousness-type double patenting.

Claims 1, 3-5, 8, 13, 15, 16, 18, 20, 22-26, 33, have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

Claims 1, 3-5, 8, 13, 15, 16, 18, 20 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

STATUS OF AMENDMENTS

No amendments to the claims have been proposed following the Final Rejection dated 12/04/2007. Accordingly, the claims on appeal are the above claims as set forth in the APPENDIX.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1: This claim relates to a method for the topical treatment of ectoparasites, their nymphs and eggs on mammalian skin and hair by applying thereto a

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water soluble or dispersible, substantially air-impermeable pharmacologically acceptable barrier composition containing at least one pesticidally active monohydric alcohol, (a) in which the composition contains from 1-50% by weight of the alcohol, (b) formulated to keep air from their breathing apparatuses, (c) applied to completely saturate the hair and skin, (d) wherein the composition can be readily rinsed out with water, and (e) the composition is free from any other pesticidally active compounds. See pages 3-6, 8 and 9 of the application.

Dependent claims 3-7 are directed to various time frames for which the composition is left in contact with the skin and hair. See page 5, line 17 – page 6, line 2.

Dependent claims 8 and 9: These claims limit the monohydric aralkyl alcohols used in the method to those of formula (I).

Dependent claim 11 limits the mammal to humans in claim 8. See page 5, lines 1-4.

Dependent claim 13 limits the composition of claim 8 to a water containing gel. See page 9, lines 11-13 and original claim 13.

Dependent claims 15 and 16, dependent on claim 8, relate to carrying out the method steps twice. See page 10, lines 15-19 and original claims 15 and 16.

Dependent claim 18 relates to carrying out step c) with water. See page 6, lines 3 and 4.

Dependent claims 20 and 21, dependent on claim 1, add additional components to the composition. See page 10, line 20 - page 11, line 7.

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Dependent claims 22-26 dependent on claim 1, set forth quantities of monohydric aralkyl alcohol present in the composition. See page 4, lines 13-19.

Dependent claims 33 and 34, dependent on claim 1, set forth time frames for step (C) of claim 1. See page 6, lines 6-7.

Dependent claims 35 and 36, dependent on claims 1 and 35 respectively, set forth kill percentages. See original claims 35 and 36 and Examples 15 and 16 on pages 24-30.

Independent claim 45: This claim is directed to a method for the topical treatment of lice, their nymphs and nits using compositions containing benzyl alcohol as the monohydric aralkyl alcohol. See e.g. page 5, lines 11-14 and page 7, lines 13-14.

Dependent claim 46, dependent on claim 45, limits the mammalian skin and hair to human skin and hair. See page 5, lines 1-4.

Dependent claim 47, dependent on claim 45, limits the contact time in which the composition is in contact with the skin and hair. See page 5, line 17 – page 6, line 2.

Dependent claims 48 and 49, dependent on claim 45 and 48 respectively, relate to carrying out the method steps twice. See page 10, lines 15-19 and original claims 15 and 16.

Dependent claim 50 dependent on claim 45, limits the lice to head lice. See page 5, lines 11-13.

Dependent claim 51, dependent on claim 45, limits step (C) to the use of water. See page 6, lines 3-4.

Dependent claim 52, dependent on claim 45, limits the composition to a water-containing gel. See page 9, lines 11-13 and original claim 13.

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Dependent claims 53 and 54, dependent on claim 45 and 53 respectively, add additional components to the composition. See page 10, line 20 - page 11, line 7.

Dependent claims 55-59, dependent on claim 45, set forth the quantities of benzyl alcohol present in the composition. See page 4, lines 13-19.

Dependent claims 60 and 61, dependent on claim 45, set forth the kill percentages for the lice. See original claims 35 and 36 and Examples 15 and 16 on pages 24-30.

Dependent claim 62, dependent on claim 45, sets forth a time period for contact of the composition with skin and hair, that the lice are head lice, and that the mammalian skin and hair is that of a human being. See claims 47, 50, and 46.

Dependent claim 63, dependent on claim 62, adds components to the composition. See claim 53.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, and 33-36 have been rejected under 35 USC 112, first paragraph as failing to comply with the enablement requirement.

Claims 45-48 and 50-63 have been rejected under 35 USC 102(b) as being anticipated by Gans et al US 2003/0040504.

Claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 have been rejected under 35 USC 103(a) as being unpatentable over Lover 4368207 and Bessette 6974584 and Cardin et al 5288483 in view of Pearlman 6303581.

Claims 1, 3-5, 8, 9, 13, 18, 20, 22-26, 33 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28, 29, 31-38 of Patent No. 6793931.

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Claims 1, 3-5, 8, 13, 15, 16, 18, 20, 22-26, 33 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-38, 44-46, 48-51, 65-81 of US application no. 10/382188.

Claims 1, 3-5, 8, 13, 15, 16, 18, 20 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 32-36, 38, 45, 47, 49, 51, 54, 56, 58 & 60 of copending Application No. 10/336457.

ARGUMENT

Before discussing the Examiner's rejections, it may be helpful to set forth the substantive sections of the Final Rejection dated 08/23/2007, the Advisory Action dated 10/22/2007, and the Advisory Action dated 12/04/2007, as a basis for arguments and to make certain that Appellant does not in any way misrepresent the Examiner's positions.

Final Rejection dated 08/23/2007

"Claim Rejections – 35 USC § 112

Claim 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained; Norval (column 3, lines 60-63; column 4, lines 13-17) show benzyl alcohol to attract some ectoparasites; ticks, while GANS shows it to be lethal to lice [0107] one would not know if any given compound would kill, attract, or repel, any given ectoparasite. LOVER shows lethality to mites, but not to lice, of 25% benzyl alcohol, while 100% is lethal to both. Clearly, each species of ectoparasite, in each developmental stage, must be tested against each species of aralkyl on dose-response curves, in order to determine if any of the species besides benzyl alcohol can meet the claim limitations of death of most ectoparasites. See example BESSETTE-US 2005/004233 – Tables 2 [0185] and [0191] show 100% kill by benzyl alcohol, but at [0197] only 60% kill in 10 minutes-species dependent effect. Additionally, efficacy is not predictable in the field from one analogue to the next (see, e.g., *In re PAPESCH* 137 USPQ 43, 48 quoting in *re SCHECTER* 98 USPQ 144, 150. We are convinced.....that, as appellants contend, there is a considerable

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degree of unpredictability in the insecticide field with homologs, isomers, and analogs of known effective insecticides having proven ineffective as insecticides." Such experimentation required would be excessive."

"Claim Rejections – 35 USC § 102

Claims 45-48, 50-63 are rejected under 35 U.S.C. 102(b) as being anticipated by GANS et al US 2003/0040504.

Benzyl alcohol [0021] is applied in gel or shampoo [0013] and kills eggs and lice [0014, 0022], and rinsed off with water [0016]. Repeated administrations are done; preferably 100% kill is obtained [0084]. Benzyl alcohol is left on up to 20 minutes [0107] and is at 0.5-20% [0108]. Exemplary air impermeable compositions are shown as VI, XII.

"Claim Rejections – 35 USC § 103

Claim 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, 45-63 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lover 4368207 and Besette 6974584 and Cardin et al 5288483, in view of Pearlman 6303581.

Note CARDIN works the compositions into the scalp and hair ((b) of column 12), the instant "sufficient to saturate" then rinsed with water (column 7, lines 5-11).

Double Patenting

Claims 1, 3-5, 8, 9, 13, 18, 20, 22-26, 33 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 28, 29, 31-38. Patent No. 6793931.

Claims 1, 3-5, 8, 13, 15, 16, 18, 20, 22-26, 33 stand are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-38, 44-46, 48-51, 65-81 of US application #10/382188.

Claims 1, 3-5, 8, 13, 15, 16, 18, 20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 32-36, 38, 45, 47, 49, 51, 54, 56, 58 & 60 of copending Application No. 10336457.

Response to Arguments

Applicant's arguments filed 6/4/07 have been fully considered but they are not persuasive; applicant argues claims are enabled. However, see rejection as maintained, with references to support the species specific effects of specific compounds.. As to the 103 rejection, arguments that the art cited does not show Benzyl alcohol to be preferred,

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nor does each of the references show Benzyl alcohol in a suffocating composition, with 99% efficacy. In fact, references are said to teach away. However, examiner finds the art shows a number of alcohols to be effective and safe, thus, useful as combined for lice control. The declaration is beyond the scope of the claims.”

Advisory Action dated 10/22/2007

“The request for reconsideration has been considered but does NOT place the application in condition for allowance because: applicant’s arguments are directed to suffocation of all life forms of all ectoparasites of mammals, caused by the substantially air-impermeable composition completely covering skin & full length of hair. However the 1.A)b) claim suggests WHEN applied to the ECTOPARASITE, they can not get air through their breathing apparati; application as would be done @ 1.A) does not necessarily apply to the parasite to prevent air intake. Thus, absent identification of the components of the barrier composition, one would need test the array of alcohols claimed with the air impermeable barriers, to identify whether in fact nymphs, eggs & adults of various species are killed. The prior art shows the one compound alcohol; the fact that other actives are present does not impune the description of the barrier components as useful with one active. The invention as is claimed is seen as evident in the prior art of record, thus all rejections of the rejection are maintained.”

Advisory Action dated 12/04/2007

“The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Rejections of record stand, for the monohydric aralkyl (claim 1) can also have any number of added functional, pesticidally active groups (cl, f, cn---) all of which would need to be tested for attractancy, repellency, lethality against each of the array of ectoparasitic species; further, > 1 such compound is permitted, thus the permutations & combinations need be tested. Note also claim 45 requires benzyl alcohol, but any other. If only minimal testing were required, the prior art also would provide this basis for the artisan of ordinary skill to achieve satisfactory treatment of lice, given the standards of recognition of common sense, evident in the recent 2007 Supreme Court KSR case; one would want to treat to kill all lice, & not have repeated infestation, such as would follow thorough washing and repeat treatment if required...”

Rejection of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, and 33-36 under 35 U.S.C. 112, first paragraph as failing to comply with the enablements requirement.

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Arguments relevant to claim 1 and generally to the claims dependent thereon.

On page 2 of the final Rejection, the Examiner has rejected claims 1, 3-9, 11, 13, 15, 16, 20-26, and 33-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner first contends that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

It is assumed that the Examiner is not rejecting the above claims for failing to find *in hoc verba* support in the specification, but rather that testing various species of monohydric aralkyl alcohols against various species of ectoparasites would involve excessive experimentation. The Examiner has nowhere contended that *in hoc verba* support is in issue, so this will not be further separately discussed.

First of all, all of the above claims require the compositions used in the method of the invention to be air impermeable (see e.g. claim 1A)) and are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses (see e.g. claim 1A)b), i.e. suffocating the ectoparasites (see e.g. page 8, lines 8-14 of the specification).

Hence suffocating the ectoparasites is clearly not species dependent, nor would suffocation depend on the particular monohydric aralkyl alcohol selected for use in the composition. Suffocation will of course kill any ectoparasite.

None of the references cited by the Examiner as support for his contention that experimentation would be excessive disclose the limitation that the compositions used in

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these references prevent the ectoparasites from obtaining air through their breathing apparatuses, or kill ectoparasites by suffocation, and hence the variable results obtained by the references' compositions are respectfully submitted to be irrelevant with respect to the presently claimed invention.

Experimentation to determine the time frame needed for killing all or at least most of any particular ectoparasite, and if present its nymphs, and/or eggs, for any particular composition used in the practice of the invention is clearly easy, straightforward, and by no means excessive. See e.g. the method of the invention disclosed on pages 3 and 4, and Examples 15, 16, and 17 on pages 24-31 of the specification, which can be readily followed for any composition and any stage of ectoparasite infestation.

The Federal Circuit Court held on February 11, 2004 in *Liebel-Flarsheim Co. v. Medrad, Inc* (Fed. Cir. 03-1082), that a feature of an invention described in a patent specification may not be imported as a limitation on a claim simply because that feature is included in the sole embodiment of the invention.

Also, as pointed out by the court in *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971), a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein which must be relied on for enabling support. How such teaching is set forth, either by the use of illustrative examples or by broad terminology is of no importance. There is no dispute

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here that the present claims find literal support in the specification.

It is respectfully submitted that in rejecting the claims under 35 U.S.C. 112, the Examiner is charged with the initial burden of providing a basis upon which to support the conclusion that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claims, when reasonably interpreted in light of the specification. See In re Moore 439 F.2d 1232, 169 USPQ 236 (CCPA 1971); In re Hammock, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). The resolution of this legal question necessarily depends upon the facts of each particular case. Smithkline Diagnostics Inc. v. Helen Laboratories Corp.; 859 F.2d 878, 8 USPQ2d (1987); Chicago Pneumatic Tool Co. v. Hughes Tool Co.; 97 F.2d 945, 38 USPQ 258 (10th Cir. 1938).

Thus, it is respectfully contended that it was incumbent upon the Examiner to substantiate, by factual evidence or sound scientific reasoning that the enabling disclosure is not commensurate in scope with the claimed invention as a whole or as to any aspect thereof. It is further respectfully contended that the Examiner has clearly failed to meet this burden.

The Examiner has provided no factual evidence nor set forth cogent scientific reasoning establishing that the claimed invention encompasses inoperable embodiments, components, or methods or that it would require undue experimentation by the skilled artisan to practice the claimed invention given the present invention. Cf. In re Skrivan, 427 F.2d 801, 116 USPQ 85 (CCPA 1970); In re Angstadt 537 F.2d 498, 190 USPQ 214 (CCPA 1976). As pointed out by the court in Skrivan, claims need not to recite factors which would be obvious to one of ordinary skill in the art.

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One skilled in the art would understand the term "ectoparasite" and the parasites included within the term. The present methods are directed to the killing of such ectoparasites, their nymphs, and their eggs by applying the composition of the invention and leaving them in contact with the ectoparasites, nymphs, and their eggs until they have been killed. Hence, those skilled in the art would clearly understand how to carry out the method of the invention with any ectoparasite.

In addition, only those ectoparasites that cause an infestation on animal skin are included, and hence the ectoparasites covered by claim 1 are limited in number.

With respect to monohydric aralkyl alcohols, one skilled in the art would have no problem in understanding what compounds fall within the scope this term, or how to use such compounds in the methods of the invention.

Hence, one skilled in the art can test any composition of possible interest falling within the scope of claim 1. There is of course no reason to test all of the compositions falling under claim 1.

In the present application, it is respectfully contended that it is not apparent why one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claims when reasonably interpreted in light of the supporting specification, for the reasons discussed above.

It is also respectfully contended that there is no "reason to doubt the objective truth of the statements contained" in the specification and claims.

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The Examiner refers to various references to buttress his position. However, none of these references disclose the presently claimed invention, and hence any problems they may have with their particular inventions are respectfully submitted to be irrelevant with respect to the presently claimed invention.

The Examiner also cites two legal precedents to support his position. However, as stated above, the present compositions kill by suffocation, which will kill any ectoparasite. The present compositions are not "insecticides", i.e. toxic chemical agents, as were the subject compounds of the references' decisions.

Hence, it is respectfully submitted that any skilled practitioner would know exactly how to carry out the claimed methods, especially in the light of the disclosures including operating Examples in the specification. Substituting another compound for benzyl alcohol would not present any enablement problems, nor would carrying out the claimed methods with an ectoparasite other than lice present any enablement problems.

There is of course no requirement that the claims must be limited to the scope of the operating examples. Operating examples are in fact not even required in order to obtain claims to an invention.

In the Advisory Action dated 10/22/2007, the Examiner contends that absent identification of the components of the barrier composition, one would need to test the array of alcohols in the air impermeable barrier to identify whether in fact nymphs, eggs and adults of various species are killed.

With respect first to the need to test the array of alcohols, since suffocation will of course kill any ectoparasite and the specification discloses how to apply the air-

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impermeable compositions of the invention, as discussed above, excessive experimentation is not required.

Concerning identification of the other components of the barrier compositions, these are not active components – the critical factors being a) that the compositions when formulated are air-impermeable (and hence any non-active components that would not prevent air-impermeability can be used in the present invention), and b) that they are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses. Enablement is clearly set forth for the method of the invention on pages 3 and 4 and Examples 15, 16, and 17 on pages 24-31 of the specification.

Advisory Action of 12/04/2007

The Examiner refers to the fact that claim 1 is broad enough to include added functional pesticidally active groups to the monohydric aralkyl alcohols.

The Examiner is correct that such groups are not excluded by the term “monohydric aralkyl alcohol”, but whether or not they are pesticidally active groups is debatable, and they may well be excluded by the term “pharmacologically acceptable” in claim 1, e.g. - C≡N groups.

Also, it is not agreed that all such possible compounds need to be tested. If there was interest in a particular compound or compounds, they could readily and easily be tested. Why would anyone want to test all possible compounds?

Also, this observation by the Examiner is not applicable to other more restricted claims such as claims 8 and 9.

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Claims 3-7: These claims are directed to time frames for contact with skin and hair for the compositions of the invention, hence adding another element to enablement.

Claims 8 and 9: These claims limit the monohydric aralkyl alcohol to those of formula (I).

There is no reason to assume that any of the groups that differ from benzyl alcohol would cause the closely related alcohols of formula (I) to be inoperative for use in the invention, e.g. that they could not function to keep ectoparasites from closing their breathing apparatuses. This is hence another element added to enablement.

Claims 15 and 16: These claims related to carrying out the claimed method twice – another element added to enablement.

Claims 22-26: These claims related to quantity ranges for the alcohol, which is another element added to enablement.

Claims 33 and 34: These claims give a time range of step (C) of claim 1, another element added to enablement.

In view of the above discussion, it is respectfully contended that claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, and 33-36 are free of enablement problems under 35 U.S.C. 112, first paragraph, and the Board is respectfully requested to so find.

Rejection of claims 45-48 and 50-63 under 35 U.S.C. 102(b) as being anticipated by Gans et al US 2003/0040504.

At the bottom of page 2 of the Final Rejection, the Examiner has rejected claims 45-48 and 50-63 under 35 USC 102 (b) as being anticipated by the Gans reference.

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Re: claim 45

The Examiner first refers to the benzyl alcohol [0021] being applied in gel or shampoo form [0013]. It should be noted, however, that benzyl alcohol in [0021] is a second active ingredient: the first active ingredient being terpene-ol. Our claims exclude other active ingredients. See e.g. claim 45 (A)(e). In addition, there is no disclosure in these sections of the use of air-impermeable compositions. This latter point will be discussed in more detail later.

The Examiner next refers to sections [0014] and [0022] as showing the killing of eggs and lice. Section [0014] does disclose the killing of eggs and lice, but requires a total of four active ingredients to achieve this result, i.e. pyrethrum, alpha terpineol and D-limonene in addition to benzyl alcohol. As pointed out above, claim 45 specifically excludes such compositions.

The Examiner contends that section [0107] discloses that benzyl alcohol “is left on up to 20 minutes.” This section says that benzyl alcohol “is effective at killing ectoparasites within about 20 minutes, or preferably less time....”. This is a disclosure that it takes close to or about 20 minutes to kill ectoparasites. The statement “or preferably less time” does not set forth the meaning of “less time”, and seems to be stating that it would be preferable if killing could take place in less than 20 minutes.

The Examiner then contends that “Exemplary air impermeable compositions are shown as VI and XII.

Example VI contains two other active components in addition to benzyl alcohol, namely, D-limonene and pine needle oil.

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Example XII contains three other active ingredients, namely, pyrethrin, piperonyl butoxide, and a terpineol.

Hence, for this reason above these compositions do not meet the requirements of claim 45.

With respect to the Examiner's contention that these are air impermeable compositions, this contention is respectfully submitted to be incorrect for the following reasons:

1. There is no basis for the assumption that these are air impermeable compositions, and the Examiner has provided no reasons for making this assumption. Clearly, the examples do not contain any such disclosure.
2. There is no suggestion or disclosure anywhere in the Gans reference that any of his compositions are air-impermeable.
3. The fact that Gans is not disclosing air impermeable compositions is shown by section [0107] which gives a time of about 20 minutes for his benzyl alcohol – containing compositions to kill ectoparasites (and no disclosure of killing their eggs or the time needed to kill their eggs). See also page 14, where it is made clear [0078] that resistance with the references' compositions is a problem, and to prevent the development of resistance in ectoparasites, the compositions should comprise "at least two active ingredients", each from a different category.

As disclosed in the present specification on page 5, time frames of only 2-10 minutes are needed for suffocating the ectoparasites. See also Example 15 (page 26, lines 18-20) where a kill rate of greater than 99% was achieved in 10 minutes. See also

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Example 16, page 30, lines 1-3 where a 10 minute treatment with a composition of the invention resulting in “excellent ovicidal activity.” See also Example 17 where a 10 minute in vitro testing on nits produced an ovicidal activity of 94.9% for one composition and 93.1% for a second composition.

It should be noted that Gans nowhere discloses the importance of complete saturation of both the scalp and the entire length of long hair in the infected areas. See e.g. page 5, lines 5-10 and the DECLARATION UNDER 37 CFR 1.132 dated 06/04/2007. The importance of this requirement will be discussed in more detail in the discussion of the 35 U.S.C. 103 (a) rejection.

In conclusion, it is respectfully contended that the Gans reference does not anticipate the method of the presently claimed invention as set forth in claim 45 since Gans does not disclose any of the following limitations:

- a) use of an air-impermeable composition;
- b) wherein the composition is formulated so that when applied to the lice, the composition prevents them from obtaining air through their spiracles;
- c) wherein the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas; and
- d) wherein the composition is free from any effective pesticidally active compounds other than benzyl alcohol, and nonetheless kills at least most of the lice, nymphs, and eggs in the infected area.

Re: claim 47: Gans does not disclose an effective contact time of 2-10 minutes.

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Re: claims 48-49: Gans does not disclose these limitations. Concerning Gans repeated administrations in section [0084], this is a very general disclosure, containing words such as “it is believed that these compositions and/or methods will also kill human ectoparasite eggs” (underlining added). It is therefore essentially meaningless with respect to any particular composition having the ability to “kill human ectoparasite eggs.”

Re: claims 55-59: Gans does not disclose these ranges for benzyl alcohol, where benzyl alcohol is the only component having effective pesticidal activity.

Re: claim 62: These limitations are not disclosed by Gans.

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The Examiner contends that the prior art (Gans?) shows the one compound alcohol and the fact that other actives are present does not improve the description of the barrier components as useful with one active. The Examiner concludes that the invention as claimed is evident in the prior art of record.

Concerning the Gans reference showing other actives, the present invention in the above claims is based on air-impermeable compositions that suffocate the lice, and the presence of benzyl alcohol that prevents the lice from closing their breathing apparatuses. Accordingly, since other actives are not needed in the present compositions, and the claims specifically exclude such other actives, the possibility of side effects and resistance developed by the lice to the other actives are eliminated, especially since the Gans' compositions do not function by suffocating the lice.

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The Examiner states that “note also claim 45 requires benzyl alcohol, but any other.” If the Examiner means that other effective alcohols can be present in the compositions, claim 45 A)e) excludes such alcohols.

The Examiner also refers to the use of common sense to supply the deficiency in the Gans reference concerning washing and repeat treatment. This comment appears to relate to claims 48 and 49. It is respectfully submitted that “common sense” is not a disclosure, and is in fact a hindsight observation. Also, even assuming, arguendo, that the Examiner’s position is correct, claims 48 and 49 are dependent on claim 45, the limitations of which are not taught or suggested by the Gans reference, as discussed above.

Rejection of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36 and 45-63 under 35 U.S.C. 103(a), as being unpatenatable over Lover 4368207 and Bessette 6974584 and Cardin et al 5288483 in view of Pearlman 6303581.

Claims 1, 11, 13, 20, 21, 46, 50, 52-54:

With respect first to the Lovers reference, this reference discloses the testing of a large number of alcohols to obtain a pediculicidal rating (as well as an ovicidal rating).

Table I-III are tables showing the screening of compounds that might be effective against lice, not a disclosure that all screened compounds are effective pediculicides.

Benzyl alcohol was tested at 100% alcohol, 25% solution, and a 15/25/60 mixture. The results obtained for benzyl alcohol show that this was not an effective

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pediculicide, and nowhere in the reference, including the claims, does the reference contend otherwise.

The Lover reference shows that even at a 100% concentration, it was still only 90% effective, i.e. 10% of the lice were left alive to rapidly reproduce.

In a 25% solution in water it had no effectiveness whatsoever, and in a 15% concentration with 25% isopropanol and 60% water, it was only 5% effective.

It should be noted that in column 5 none of the "typical formulations" contained benzyl alcohol nor any other monohydric aralkyl alcohols.

See also column 2, lines 8-11 where it states that "accordingly, when both pediculicidal and ovicidal activity is desired, it is preferred to employ an unsubstituted alkyl alcohol having a log p value of 2.13-5.1". Benzyl alcohol and other monohydric aralkyl alcohols are not "unsubstituted alkyl alcohol(s)", and benzyl alcohol has a p value of 1.10. Here again, Lover directs away from the use of benzyl alcohol.

Clearly the above results direct one skilled in the art away from the use of benzyl alcohol or other monohydric aralkyl alcohols as a pediculicide.

Concerning phenyl ethanol, this compound was 100% effective against lice when 100% alcohol was used. Claim 1 does not include the use of 100% alcohol, nor anywhere close to 100% alcohol.

In a 25% solution, effectiveness was 0%. The present compositions are highly effective at concentrations much below 25%.

It should further be noted that Lover's claims do not include phenyl ethanol, i.e. Lover does not include phenyl ethanol as an effective agent for controlling lice.

With respect to claim 1, the limitations in claim 1 not taught or suggested by the
Lover reference include the following:

1. The limitation in paragraph A)a) of a weight range of monohydric aralkyl alcohol of from 1 to 50%. Lover shows that even at 100% concentration benzyl alcohol is only 90% effective as a pediculicide. Appellant has shown extremely high effectiveness levels for the different compositions of the invention. See e.g. Example 15 on pages 24-27 where a composition containing only 5% by weight of benzyl alcohol (Example 1 composition) produced kill rates of greater than 99% against lice. See also Example 16 on pages 27-30 where a composition of the invention also containing only 5% by weight of benzyl alcohol (Example 2 composition) produced a kill rate of 100% against lice.
2. Subparagraph A)b) wherein the compositions are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses. It has been discovered that the combination of the pesticidal activity of the aralkyl alcohols of the invention when present in compositions that suffocate the ectoparasites provide very high kill rates (over 99%) in very short contact times. The aralkyl alcohols have been found to prevent the ectoparasites from closing their breathing apparatuses (see e.g. page 6 lines 15-19), and this effect combined with the suffocating effect of compositions that prevent air from entering the ectoparasites' breathing apparatuses (spiracles in lice) results in these very high kill rates. There is

of course no teaching or suggestion in Lover for the concept of using compositions that suffocate the ectoparasites (see e.g. col. 2 lines 25-30 where it is stated that “Any pharmaceutically acceptable carrier” can be used).

3. The limitation in subparagraph A)c), i.e., the discovery that these very high kill rates are obtained when both the hair and skin in the infected areas are completely saturated with the compositions of the invention. Here again there is no such disclosure in the Lover reference and clearly not with respect to this limitation applied to the compositions of the present invention. With respect to this limitation the Declaration under 37 CFR § 132 proves the unexpected importance of this limitation. Please see page 5, lines 8-10 of the specification where the term “completely saturate” means “that substantially all strands of hair are fully saturated with the composition, along their entire length, and the skin in the infected area is also completely coated with the composition.”

It should also be noted that it was discovered that lice can recognize the present treatments as a possible threat, and applying the compositions of the invention to scalp or hair in the vicinity of the scalp causes at least some of the lice to immediately and rapidly migrate to untreated areas, i.e. move to untreated areas along the entire lengths of long hairs in the infested areas. Hence, thorough saturation of the entire lengths of long hairs in the infested areas was found to be necessary in order to kill the migrated lice in order to achieve a very high kill ratio. This finding was unexpected and unobvious.

4. The limitation that the composition is free from any pesticidally active compounds other than the pesticidally active alcohol of the invention.

There is nothing in Lover that is directed to this limitation.

It should also be noted as stated above that the very short contact times of from 2 to 10 minutes are generally sufficient to achieve the above very high kill rates. See e.g. page 5, line 17 – page 6, line 2 of the specification.

It should further be noted that the presently claimed compositions will function effectively even if the ectoparasites become resistant to any pesticidal activity of the monohydric aralkyl alcohols since they cannot become resistant to asphyxiation, which can provide a kill rate greater than 99%, and usually 100% (see page 10 lines 7-11). There is no such teaching or suggestion in the Lover reference that would lead to this concept.

It is also contended that Lover teaches away from the use of either benzyl alcohol or phenyl ethanol.

The U.S. Court of Appeals for the Federal Circuit in In re Gurley, 31 USPQ 2d 1131 held that “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” See also In re Braat, 16 USPQ 2d 1812, where the CAFC held that one important indicium of nonobviousness is teaching away from a claimed invention in the prior art.

It is respectfully contended that Lover discourages one of ordinary skill from the use of benzyl alcohol and phenyl ethanol.

In summary, the Lover reference does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

It is well settled law that all limitations must be considered in considering obviousness under 35 U.S.C. 103; it is error to ignore specific limitations distinguishing over the references. See e.g. In re Boe and Duke (CCPA) 184 USPQ 38.

Claims 3-7: These claims are directed to the very short contact times that achieve the benefits of the invention. Lover contains no such disclosure, nor would any such disclosure apply to the presently claimed invention.

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Claims 8 and 9: Lover does not disclose monohydric aralkyl alcohols of formula (I), and the two he does disclose are disclosed as what not to use in his invention.

Claims 15, 16, 48, and 49: Lover does not disclose two treatments.

Claims 22-26, and 55-59: Lover does not disclose such effective ranges for monohydric aralkyl alcohols or benzyl alcohol for use in the air-impermeable compositions of the present invention.

Claims 33-34: No such disclosure of rinsing times in Lover's patent.

Claims 35 and 36: No such kill rates are disclosed by Lover.

Claim 45: This claim is limited to lice, their nymphs and nits, and to benzyl alcohol as the at least one monohydric alcohol. All of the arguments presented above for claim 1 are applicable to claim 45 and will not be repeated to avoid redundancy. Also, the DECLARATION specifically shows unobviousness over the Lover reference.

Claim 47: No such time frame is disclosed by Lover.

Claim 51: No such step is disclosed by Lover.

Claims 60-61: No such kill rates are disclosed by Lover.

Claim 62 and 63: These limitations are not disclosed by Lover.

Claims 1, 11, 13, 20, 21, 46, 50, 52-54:

With respect to the Bessette reference, this reference discloses benzyl alcohol as one of a list of plant essential oils. A preferred embodiment is a mixture of benzyl alcohol and pyrethrins (see col. 3, lines 39-45).

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In the test results given in Example 1., column 7, only benzyl alcohol in combination with pyrethrins (the latter being excluded from claim 1) gave “very good kill”. Other benzyl alcohol containing compositions (i.e. compositions G and H) were rated as less effective than compositions A-D, without any indication as to whether Kill or Repellancy was being measured.

Accordingly, the only composition where a Kill rating is given is composition A which is clearly excluded by the present claims (“free from pesticides other than any pesticidal activity provided by the at least one monohydric alcohol”).

In addition to the above, there is no disclosure in Bessette of:

- a) an air-impermeable composition;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and

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- g) the importance of complete saturation of the hair and skin in the infected areas. See also the DECLARATION discussed in detail in the discussion of the Lover reference.

It is therefore respectfully contended that Besette does not teach or suggest the presently claimed method of the above claims.

Claims 3-7: No disclosure in Besette of such contact times of the compositions of the invention free from other actives.

Claims 8 and 9: monohydric aralkyl alcohols of formula (I) are not disclosed in the Besette reference.

Claims 15, 16, 48 and 49: Besette does not disclose two treatments.

Claims 22-26 and 55-59: Besette does not disclose such effective ranges for the aralkyl alcohols or benzyl alcohol for use in the air-impermeable compositions of the invention.

Claims 33-34: No such disclosure of rinsing times in Besette's patent.

Claims 35-36: No such kill rates are disclosed by Besette.

Claim 45: All of the arguments presented above for claim 1 are equally applicable to claim 45, and the DECLARATION specifically shows unobviousness over the teachings of the Besette reference.

Claim 47: No such time frame is disclosed by Besette.

Claim 51: No such step is disclosed by Besette.

Claims 60-61: No such kill rates are disclosed by Besette.

Claims 62-63: These limitations are not disclosed by Besette.

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Claims 1, 11, 13, 20, 21, 46, 50, 52-54:

Concerning the Cardin reference, this reference discloses ovicidal/pediculicidal anti-lice compositions containing quarternary ammonium salts, long chain fatty amines, and mixtures thereof with alkanol synergizers selected from phenyl C₂-C₆ alkanols, phenyl C₂-C₆ diols, and mixtures thereof.

The alkanols are never used alone, and their only disclosed function is to act as synergizers for the ammonium compounds and amines, which are the chemical pediculicides. See e.g. column 3, lines 21-22, where it is stated that "In the present invention, alkanol synergizers enhance the efficacy of the active compositions". (underlining added).

Claim 1 contains the limitation that no pesticides are present in the compositions used in the method of the invention other than any pesticidal activity provided by the monohydric aralkyl alcohols, hence excluding the compositions of Cardin, in which the ammonium compounds and amines are chemical pediculicides (see e.g. col. 3 above and col. 2, lines 43-45).

The Examiner refers to the Cardin reference as showing that the compositions of this reference are worked into the scalp and hair (col 12, step (b)) and that this disclosure meets the "sufficient to saturate" limitation in the present claims.

However, the above disclosure relates to compositions significantly different from those used in the present method and hence the above disclosure is not relevant to the presently claimed method. In addition, it is not agreed that the Cardin disclosure meets the requirements of complete saturation of the hair and skin in the present method. See

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page 5, lines 8-10 where the term “completely saturate” used in the claims means that “substantially all strands of hair are fully saturated with the composition along their entire length, and the skin in the infected area is also completely coated with the composition.” There are no grounds for assuming that the disclosure of “working said composition through the hair and scalp” meets the above test for completely saturate.

In addition, the DECLARATION UNDER 37 CFR 1.132 shows the unexpected criticality of making certain that even the longest strands of hair are completely saturated with the present compositions, which is clearly not disclosed by Cardin.

Cardin does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the skin and hair. See the above discussion of the DECLARATION.

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It is therefore respectfully contended for the reasons given above that Cardin does not teach nor render obvious the presently claimed method of claim 1.

Claims 3-7: No teachings in Cardin of the short contact times that achieve the benefits of the invention.

Claims 8 and 9: Cardin does not disclose monohydric aralkyl alcohols of formula (I).

Claims 15, 16, 48, and 49: Cardin does not disclose two treatments.

Claims 22-26 and 55-59: Cardin does not disclose such effective ranges for monohydric aralkyl alcohols or benzyl alcohols for use in the air-impermeable composition of the present invention.

Claims 33-34: No such disclosure of rinsing times in Cardin's patent.

Claims 35 and 36: No such kill rates are disclosed by Cardin.

Claim 45: This claim is limited to lice, their nymphs and nits, and to benzyl alcohol as the at least one monohydric alcohol. All of the arguments presented above for claim 1 are applicable to claim 45 and will not be repeated to avoid redundancy.

In addition, Cardin discloses only phenyl C₂-C₆ alkanols. Benzyl alcohol is a phenyl C₁ alkanol. Hence, this reference is completely irrelevant with respect to claims 45-63, which are all limited to benzyl alcohol.

Also, the DECLARATION specifically shows unobviousness over the Cardin reference.

Claim 47: No such time frame is disclosed by Cardin.

Claim 51: No such step is disclosed by Cardin.

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Claims 60-61: No such kill rates are disclosed by Cardin.

Claim 62 and 63: These limitations are not disclosed by Cardin.

With respect to the Pearlman reference, the “in view of” reference, this reference is directed to driable pediculostatic agents that elicit an “immersion reflex” in lice to immobilize them. The pediculostatic agents are then dried to kill at least some of the lice. The driable pediculostatic agents used in Pearlman’s invention are “surfactants, lipid materials and alkanols” (col. 10, lines 48-51). The alkanols within the scope of the invention are disclosed in col. 12, lines 52-65, and appear to be any “nonvolatile fatty alcohol”. Monohydric aralkyl alcohols are not disclosed.

Pearlman does not disclose any of items a) through g) disclosed above in discussion of the other references.

Accordingly, the Pearlman reference is respectfully contended to contain no disclosures relevant to the presently claimed invention.

The Examiner is taking a driable unrelated pediculostatic agent from the Pearlman reference and combining this with the substantially ineffective compositions of the Lover, Bessette, and Cardin references all without any teaching or suggestion in any of these references to do so, completely out of context, and concluding that the present compositions and methods are thereby obtained, which is respectfully submitted to be incorrect for all the reasons discussed above. This rejection is contended to be a hindsight rejection using the present invention as a template.

It is of course improper to rebuild references, in light of applicant’s disclosure, in order for it to operate in a manner never intended or contemplated by the reference. Ex

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parte Garrett, POBA (1961) 132 USPQ 514. In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. In re Avery, 186 USPQ 161. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. In re Schaffer (CCPA 1956) 108 USPQ 326, In re Skoll (CCPA 1975) 187 USPQ 481. The mere fact it is possible for two isolated disclosures to be combined does not render the result of that combination obvious absent a logical reason of record which justifies the combination. In re Regal et al. (CCPA 1975) 188 USPQ 136.

It is respectfully contended that the Examiner has not provided a sufficient basis upon which to conclude that one having ordinary skill in the art would have been led to modify the applied references to arrive at the claimed method. In re Newell, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989), In re Laskowski, 871 F.2d 115, 10 USPQ2d 1397 (Fed. Cir. 1989).

In addition, it is not apparent and the Examiner does not explain why the disclosed processes in the prior art would inherently (necessarily) yield the same product used in the present method claims. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 USPQ 59 (CCPA 1976).

There is data in the specification which reveals that products used in the claimed method exhibit properties (e.g. ability to keep breathing apparatuses from closing and the ability to suffocate ectoparasites) which are not exhibited by those prepared in accordance with any process disclosed in the references. Uniroyal, Inc.

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v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281.

The Board's attention is respectfully directed to operating Examples 1-14 where compositions containing benzyl alcohol are set forth, and Examples 15, 16, and 17 where the compositions of Examples 1, 2, 5 and 6 were evaluated clinically against lice, nymphs, and/or nits wherein each subject (lice infected) had two 10 minute treatments one week apart in Examples 15 and 16, resulting in 100% effectiveness; and Example 17 where a 10 minute treatment against nits resulted in ovicidal activity of 94.9% for the composition of Example 5 and 93.1% for the composition of Example 6.

To summarize: Lover shows benzyl alcohol as ineffective as a licide for all practical purposes. Cardin requires the presence of chemical amine and ammonium pediculicides and discloses certain alcohols as synergizers for the above chemical pediculicides. Bessette shows that only benzyl alcohol in combination with pyrethrins was effective.

In addition, the references do not disclose or suggest any of items a) through g) set forth above in discussions of individual references, i.e. none of the references, either singly or in combination, disclose a method for using compositions to kill ectoparasites in which:

- a) an air-impermeable composition is employed;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;

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- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action include suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

On page 4 of the Final Rejection, the Examiner contends that the art shows a number of alcohols to be effective and safe, thus useful as combined for lice control. If the Examiner is taking the position that alcohols other than monohydric aralkyl alcohols are effective, and can be combined with the present alcohols, then the present claims exclude their presence in the compositions used in the present invention. See e.g. claim 1 A)e). If the Examiner means that the references can therefore be combined, then as discussed above, there is no teachings or suggestions in any of the references for such a combination, nor does any such combination lead to the presently claimed invention.

The Examiner also states that the declaration is beyond the scope of the claims. This contention is not understood since it is contended that the declaration falls within the scope of all of the claims.

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In this Advisory Action, the Examiner refers to claim 1 A)b) as saying when applied. However, claim 1 A)c) makes it clear that the composition is applied and hence prevents the ectoparasites from obtaining air through their breathing apparatus.

Concerning the Examiner's position that the array of alcohols claimed would have to be tested, as discussed above there is no reason to do so – any formulation of interest meeting the other requirements of the claims can readily be tested.

With respect to the Examiner's contention that the claimed invention is evident from the prior art of record, none of the prior art, either singly or in combination, discloses a method for using compositions to kill ectoparasites in which:

- a) an air-impermeable composition is employed;
- b) containing at least one monohydric aralkyl alcohol in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action include suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and

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- g) the importance of complete saturation of the hair and skin in the infected areas.

In view of the above discussion, the Board is respectfully requested to find for Appellant with respect to the 35 U.S.C. 103 (a) rejection of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63.

Rejection of claims 1, 3-5, 8, 9, 13, 18, 20, 22-26 and 33 for nonstatutory obviousness-type double patenting as being unpatentable over claims 28, 29 and 31-38 of Patent no. 6, 793, 931.

Since all of the claims other than claim 1 are dependent or ultimately dependent on claim 1, the limitations in claim 1 that are not present or disclosed in the U.S. 6, 793, 931 claims are discussed below with respect to the issue of the obviousness or lack of obviousness of these claimed features.

The above patented claims do not contain at least the following limitations in present claim 1:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves. The fact that compositions are found to be effective against ectoparasites does not mean that they are also effective against ectoparasite eggs.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with this brief, and discussed

above. It is respectfully contended that this was an unobvious discovery and nothing in the '931 claims render this limitation obvious.

3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites). There is nothing in the claims of the '931 patent that would render this limitation concerning ectoparasite eggs obvious.
4. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '931 patent are limited to the treatment of lice and it is therefore not obvious from the claims that the compositions can include the treatment of ectoparasites other than lice.

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above patent, and the Board is respectfully requested to so find.

Rejection of claims 1, 3-5, 8, 13, 15, 16, 18, 20, 22-26 and 33 for provisional rejection for nonstatutory obviousness-type double patenting over claims 33-38, 44-46, 48-51, and 65-81 of U.S. application no. 10/382, 188.

Since all of the claims other than claim 1 are dependent or ultimately dependent on claim 1, the limitations in claim 1 that are not present or disclosed in the claims of SN 10/382, 188 are discussed below with respect to the issue of the obviousness or lack of obviousness of these claimed features.

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The above application claims do not contain at least the following limitations in present claim 1:

1. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with this brief, and discussed above. It is respectfully contended that this was an unobvious discovery and nothing in the '188 claims render this limitation obvious.
2. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '188 application are all limited to the treatment of lice and it is therefore not obvious from these claims that the compositions can include the treatment of ectoparasites other than lice.

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above application, and the Board is respectfully requested to so find.

Rejection of claims 1, 3-5, 8, 13, 15, 16, 18 and 20 for nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 32-36, 38, 45, 47, 49, 51, 54, 56, 58, and 60 of copending application no. 10/336, 457 (now U.S. Patent no. 7, 294, 342).

Since all of the claims other than claim 1 are dependent or ultimately dependent on claim 1, the limitations in claim 1 that are not present or disclosed in the claims of the above patent are discussed below with respect to the issue of the obviousness or lack of obviousness of these claimed features.

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The above patented claims do not contain at least the following limitations in the present claim 1:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves. The fact that compositions are found to be effective against ectoparasites does not mean that they are also effective against ectoparasite eggs.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 DECLARATION included with this brief, and discussed above. It is respectfully contended that this was an unobvious discovery and nothing in the '342 claims render this limitation obvious.
3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites). There is nothing in the claims of the '342 patent that would render this limitation concerning ectoparasite eggs obvious.
4. The present claims are directed to the topical treatment of ectoparasites (not just lice). The claims of the '342 patent are limited to the treatment of lice and it is therefore not obvious from these claims that the compositions can include the treatment of ectoparasites other than lice.

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above patent, and the Board is respectfully requested to so find.

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The Board is respectfully requested to find for Appellant with respect to the patentability of the claims on appeal.

Respectfully submitted,

A handwritten signature in cursive script that reads "Henry E. Millson, Jr." The signature is written in dark ink and is positioned above a horizontal line.

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CLAIMS APPENDIX

CLAIMS ON APPEAL

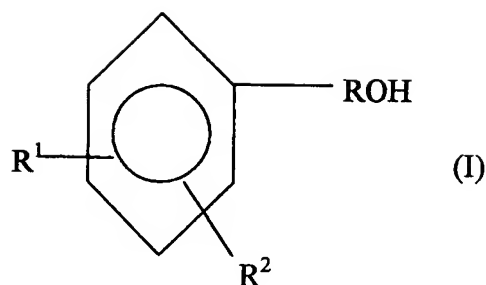
1. A method for the topical treatment of ectoparasites, their nymphs, and their eggs, on mammalian skin and hair comprising the steps of:
 - A) applying a water soluble or water-dispersible, substantially air-impermeable, pharmacologically acceptable barrier composition containing at least one pesticidally-active monohydric aralkyl alcohol to areas of mammal skin and hair infected with ectoparasites wherein
 - a) the composition contains a quantity in the range of from about 1 to about 50% by weight of the at least one monohydric aralkyl alcohol sufficient to provide pesticidal activity against the ectoparasites, their nymphs, and their eggs,
 - b) the composition is formulated so that when applied to the ectoparasites, the composition prevents them from obtaining air through their breathing apparatuses,
 - c) the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas,
 - d) the composition can be readily washed out of the infected areas by rinsing with water, and

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- e) the composition is free from any effective pesticidally active compounds other than the at least one pesticidally-active monohydric aralkyl alcohol, and
 - B) leaving the composition in contact with the skin and hair in the infected area until at least most of the ectoparasites, nymphs and eggs have been killed; and
 - C) removing the composition, the dead ectoparasites, and dead nymphs from the skin and hair with water or other aqueous based liquid.
3. The method of claim 1 wherein in step B) the composition is left in contact with the skin and hair for a period of at least about 2 minutes.
 4. The method of claim 3 wherein the composition is left in contact with the skin and hair for a period of at least about 3 minutes.
 5. The method of claim 3 wherein the composition is left in contact with the skin and hair for a period of at least about 5 minutes.
 6. The method of claim 3 wherein the period is from about 2 minutes to about 10 minutes.
 7. The method of claim 3 wherein the composition is left in contact with the skin and hair for a period of from about 3 minutes to about 9 minutes.
 8. The method of claim 1 wherein in step A) the at least one monohydric aralkyl

alcohol has the formula:



- wherein R is a C_1 - C_{12} straight or branched chain, saturated or olefinically unsaturated alkylene group, and R^1 and R^2 are independently selected from the group consisting of hydrogen, halogen, C_1 - C_4 alkyl, and C_1 - C_4 alkoxy groups.
9. The method of claim 8 wherein in formula (I) R is a C_1 - C_6 saturated alkylene group.
 11. The method of claim 1 wherein the mammal is a human being.
 13. The method of claim 1 wherein the composition is in the form of a water-containing gel.
 15. The method of claim 1 wherein the method steps are carried out once, and then again after a time interval.
 16. The method of claim 15 wherein the time interval ranges from about 1 week to about 3 weeks.
 18. The method of claim 1 wherein step C) is carried out by rinsing with water.

20. The method of claim 1 wherein the composition in step A) also contains at least one of the following additional components:
- a film forming agent,
 - a surface active agent,
 - a gelling or thickening agent.
21. The method of claim 20 wherein the composition contains all of said additional components.
22. The method of claim 1 wherein the composition in step A) contains from about 1% to about 20% by weight of the at least one monohydric aralkyl alcohol, based on the weight of the composition.
23. The method of claim 1 wherein the composition in step A) contains from about 2 to about 20% by weight of at least one monohydric aralkyl alcohol.
24. The method of claim 1 wherein the composition in step A) contains from about 2 to about 9% by weight of at least one monohydric aralkyl alcohol.
25. The method of claim 1 wherein the composition in step A) contains from about 3 to about 7% by weight of at least one monohydric aralkyl alcohol.
26. The method of claim 1 wherein the composition in step A) contains from about 4 to about 6% by weight of at least one monohydric aralkyl alcohol.
33. The method of claim 1 wherein step C) is carried out for from about 1 to about 5 minutes.

34. The method of claim 1 wherein step C) is carried out for from about 1 to about 3 minutes.
35. The method of claim 1 wherein more than 95% of the ectoparasites are killed.
36. The method of claim 35 wherein more than 99% of the ectoparasites are killed.
45. A method for the topical treatment of lice, their nymphs, and their nits on mammalian skin and hair comprising the steps of:
 - A) applying a water soluble or water-dispersible, substantially air-impermeable pharmacologically acceptable composition containing benzyl alcohol to areas of mammal skin and hair infected with lice wherein
 - a) the composition contains a quantity in the range of from about 1 to about 50% by weight of benzyl alcohol sufficient to provide pesticidal activity against the ectoparasites, their nymphs, and their eggs,
 - b) the composition is formulated so that when applied to the lice, the composition prevents them from obtaining air through their spiracles,
 - c) the composition is applied to the infected areas in a quantity sufficient to completely saturate both the hair and the skin in the infected areas,

- d) the composition can be readily washed out of the infected areas by rinsing with water,
 - e) the composition is free from any effective pesticidally active compounds other than benzyl alcohol, and
 - B) leaving the composition in contact with the skin and hair in the infected area until at least most of the lice, nymphs, and nits have been killed; and
 - C) removing the composition and the dead lice and nymphs from the skin and hair with water or other aqueous based liquid.
46. The method of claim 45 wherein the mammalian skin and hair is human skin and hair.
47. The method of claim 45 wherein step B) the composition is left in contact with the skin and hair for a period of from about 2 minutes to about 10 minutes.
48. The method of claim 45 wherein the method steps are carried out once, and then again after a time interval.
49. The method of claim 48 wherein the time interval ranges from about 1 week to about 3 weeks.
50. The method of claim 45 wherein the lice are head lice.
51. The method of claim 45 wherein step C) is carried out by rinsing with water.
52. The method of claim 45 wherein the composition is in the form of a water-containing gel.

53. The method of claim 45 wherein the composition in step A) also contains at least one of the following additional components:
- a film forming agent,
 - a surface active agent,
 - a gelling or thickening agent.
54. The method of claim 53 wherein the composition contains all of said additional components.
55. The method of claim 45 wherein the composition in step A) contains from about 1% to about 20% by weight of benzyl alcohol, based on the weight of the composition.
56. The method of claim 45 wherein the composition in step A) contains from about 2 to about 20% by weight of benzyl alcohol.
57. The method of claim 45 wherein the composition in step A) contains from about 2 to about 9% by weight of benzyl alcohol.
58. The method of claim 45 wherein the composition in step A) contains from about 3 to about 7% by weight of benzyl alcohol.
59. The method of claim 45 wherein the composition in step A) contains from about 4 to about 6% by weight of benzyl alcohol.
60. The method of claim 45 wherein more than 95% of the lice are killed.
61. The method of claim 45 wherein more than 99% of the lice are killed.

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62. The method of claim 45 wherein in step B) the composition is left in contact with the skin and hair for a period of at least about 2 minutes; the lice are head lice; and the mammalian skin and hair is that of a human being.
63. The method of claim 62 wherein the composition in step A) also contains at least one of a film forming agent, a surface active agent, and a gelling or thickening agent.

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EVIDENCE APPENDIX

A DECLARATION UNDER 37 CFR 1.132, dated 06/04/2007 was submitted to the Examiner on 06/04/2007. A copy of the declaration is attached hereto.

The declaration was entered in the record by the Examiner in the Final Rejection dated 08/23/2007 in the "Response to Arguments."

PATENT
Docket SU 103 US

In re: Application of Michael J. Precopio

Serial No. 10/519,972
Filed: 12/23/2004

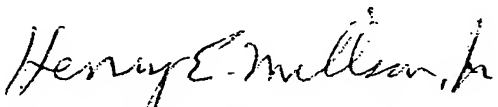
Examiner: Neil Levy
Art Unit: 1615

Title: METHODS FOR TREATING ECTOPARASITE INFECTIONS ON THE
MAMMALIAN BODY

FAX CERTIFICATION

I hereby certify that this correspondence is being telefaxed to: Commissioner for
Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450; on 06/04/2007
at fax number 571-273-8300.

Date: 06/04/2007


Signature of certifier

Henry E. Millson, Jr.
Printed or typed name of certifier

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR 1.132

Michael J. Precopio hereby declares that: He was granted a Bachelor of Arts
degree in chemistry with a minor in business administration from the University of
Delaware in 1982; He has been President of Summers Laboratories, Inc. for the past 20
years, and currently holds that position;

He is the sole inventor of the invention set forth in U.S. application Serial No.
10/519,372, entitled METHODS FOR TREATING ECTOPARASITE INFECTIONS ON
THE MAMMALIAN BODY.

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The following two studies were carried out under his supervision and control;

The compositions used in both of the studies had the following components:

<u>Component</u>	<u>% by weight</u>
Purified water	84.25
Benzyl alcohol, NF	5.00
Mineral Oil 5LT, NF	5.00
SPAN® 80, NF (sorbitan mono-oleate)	2.50
TWEEN® 80 NF (polysorbate 80)	2.50
CARBOPOL® 934 P, NF (carboxy polyethylene)	0.25
TROLAMINE® NF (triethanolamine)	0.50
	100.00

STUDY 1

An evaluator-marked, comparative, parallel, single-site study was carried out to evaluate the efficacy and safety of the above composition as a lice asphyxiator for the treatment of head lice.

The hair and skin on the heads of eighty-one (81) subjects, both males and females between the ages of 2 and 70 having a active infestation of *Pediculus capitis* (head louse) with at least 3 live lice and 10 eggs were topically treated with the above composition for 10 minutes, after which the composition was rinsed off with water, followed by another similar 10 minute treatment one week later. Seventy-nine subjects completed the study.

The primary efficacy measurement was the percentage of subjects who were confirmed as a treatment success based on the presence or absence of live lice.

At the end of the study (day 15 of the study), a 70% overall treatment success resulted (primary efficacy).

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A kill rate (%) was also determined which is the total number of lice minus the number of live lice over the total number of lice.

At the end of the study (day 15 of the study) the kill rate was 89%.

STUDY 2

An identical study to that of Study 1 above was carried out except that forty-four (44) subjects, both males and females between the ages of 2 and 70 having an active infestation of *Pediculus capitis* (head louse) with at least 3 live lice and 10 eggs were used in the study, and the quantity of the composition was adjusted for each subject so that complete saturation of the entire length of each subjects hair was obtained.

At the end of the study (day 15 of the study), a 100% treatment success resulted (primary efficacy).

The results of the above studies shows that complete saturation of the entire length of each subject's hair is essential to obtain the very high treatment success (100%) and kill rate (greater than 99%) found in Study 2.

The results obtained in Study 1 were found to have resulted from incomplete saturation of the entire length of the long hairs in the subject population of that study.

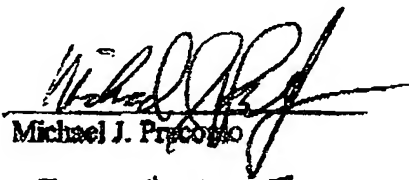
The above finding, i.e. that the entire lengths of the subject's hair must be completely saturated with the compositions of the invention to obtain very high treatment success and kill rates, was unexpected and unobvious.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.



Michael J. Prisco

June 4, 2007
Date

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RELATED PROCEEDINGS APPENDIX

none